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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,527	10/09/2003	Gordon H. Williams	NO.C-34171	2934

7590 11/24/2006

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,527	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-215* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-215* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

(1) Group I, claims 1-37 are drawn to a method for the treatment or prophylaxis of aldosterone-mediated pathogenic effects, comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has a sub-normal endogenous aldosterone level and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(2) Group II, claims 1, 38-78 are drawn to a method for the treatment or prophylaxis of aldosterone-mediated pathogenic effects, comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has salt sensitivity and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(3) Group III, claims 1, 79-118 are drawn to a method for the treatment or prophylaxis of aldosterone-mediated pathogenic effects, comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has an elevated dietary sodium intake and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(4) Group IV, claims 119-145 are drawn to a method for the treatment or prophylaxis of hypertension comprising administering aldosterone antagonist, an epoxy-

steroidal compound wherein the subject has salt sensitivity or an elevated dietary sodium intake and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173.

(5) Group V, claims 146-174 are drawn to a method for the treatment or prophylaxis of cardiovascular disease wherein the subject has salt sensitivity or an elevated dietary sodium intake and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173.

(6) Group VI, claims 175-201 are drawn to a method for the treatment or prophylaxis of heart failure wherein the subject has salt sensitivity or an elevated dietary sodium intake and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173.

(7) Group VII, claims 202-203 are drawn to a method for the prophylaxis of one or more aldosterone-mediated pathogenic effects, wherein the subject has one or more conditions such as sub-normal endogenous aldosterone level, salt sensitivity and an elevated dietary sodium intake comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has a sub-normal endogenous aldosterone level and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(8) Group VIII, claims 204-205 are drawn to a method for the treatment or prophylaxis of salt sensitivity, comprising administering aldosterone antagonist, an epoxy-steroidal compound and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(9) Group IX, claims 206-207 are drawn to a method for reducing sodium appetite in a human subject in need thereof, comprising administering aldosterone antagonist, an epoxy-steroidal compound and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(10) Group X, claims 208–209 are drawn to a method for reducing or reversing the progression of salt sensitivity, comprising administering aldosterone antagonist, an epoxy-steroidal compound and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(11) Group XI, claims 210-211 are drawn to a method for the treatment or prophylaxis of a human subject to reduce or prevent one or more pathogenic effects resulting, from aberrant aldosterone levels in brain, comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has salt sensitivity or an elevated dietary sodium intake and is classified in class 514 and subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(12) Group XII, claims 212-213 are drawn to a method for the treatment or prophylaxis of a human subject to reduce or prevent one or more pathogenic effects resulting, from aberrant sodium retention in the kidney, comprising administering aldosterone antagonist, an epoxy-steroidal compound wherein the subject has salt sensitivity or an elevated dietary sodium intake and is classified in class 514 and

subclass 172, in class 514 and subclass 588, in class 514 and subclass 173 and in class 514 and subclass 175.

(13) Group XIII, claim 214 is drawn to a method for the treatment of salt sensitive hypertension, comprising administering to the subject a therapeutically effective amount of eplereneone.

(14) Group XIV, claim 215 is drawn to a method for the treatment of salt sensitive heart failure, comprising administering to the subject a therapeutically effective amount of eplereneone.

The inventions are distinct, each from the other because of the following reasons: Inventions I to XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each set of claims in Groups I to Group XIV are directed to methodologies that are divergent in function and end effects. Accordingly, they are directed to different functions or different effects.

If applicant elects a group from Groups I –XIV, applicant is further required to elect a single disclosed species from claims 3, 36, 77, 80, 117, 144, 173, 200, 202 accordingly. If applicant elects group I, applicant is further required to elect a single disclosed species, a pathogenic effect from claim 3 and further elect a compound from claim 36. If applicant elects group II, applicant is further required to elect a single disclosed species, a pathogenic effect from claim 41 and further elect a single compound from claim 77. If applicant elects group III, applicant is further required to

elect a pathogenic effect from claim 80 and further elect a single compound from claim 117. If applicant elects group IV, applicant is further required to elect a single compound from claim 144. If applicant elects group V, applicant is further required to elect a single compound from claim 173. If applicant elects group VI, applicant is further required to elect a single compound from claim 200. If applicant elects group VII, applicant is further required to elect a pathogenic effect and further elect a single condition from the group consisting of sub-normal endogenous aldosterone level, salt sensitivity and an elevated dietary sodium intake from claim 202.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for other groups, restriction for examination purposes as indicated is proper. The searches of Groups I to XIV may be overlapping but there is no reason to believe that the searches would be co-extensive. The

examiner will be focusing on the method for the treatment or prophylaxis of aldosterone-mediated pathogenic effects wherein the subject has a sub-normal endogenous aldosterone level for searching for Group I. Conversely, in searching Group II, the examiner will be focusing on the method for the treatment or prophylaxis of aldosterone-mediated pathogenic effects wherein the subject has salt sensitivity.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election

A telephone call to the attorney is not required where 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since the examiner knows from past experience that written restriction is preferred, a telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER